Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 21 is finally rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 21, the phrase while not impeding permeation of sterilizing gases" is indefinite because the friction enhancing material is applied on the impermeable material and such impermeable material is impermeable to sterilizing gases by definition (claim 20, line 6).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 6-9, 17 and 19 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Soto et al. (5,866,069; hereinafter Soto'069). Soto'069 discloses a sterilization package for enclosing a device such as medical products (column 1, lines 14-16 and column 1, lines 27-30) during a sterilization procedure and storing the device in sterile form thereafter (column 1, line 66 to column 2, line 4), the package comprising a barrier film (colubmn 2, lines 42-52 and column 3, lines 52-54) defining an interior space, the barrier film sealing the interior space from contaminating microorganisms and at least a portion of the barrier film formed from

TYVEK which is considered equivalent to a semi-permeable material that permeable to sterilizing gasses (column 1, lines 66-67) and impermeable to contaminating microorganisms and at least a portion of an outer surface of the package is treated with silicone (column 3, lines 52-57) to render the package liquid repellent and able to withstand exposure to an oxidizing plasma sterilizing process. Since the outer surface of the package of Soto'069 is treated with silicone which is considered equivalent to the package having thereon a friction enhancing material (see claims 7 and 8) and the silicone can be applied by spraying to the outer surface of the package while not impeding permeation of sterilized gases (column 4, 37-47) which is considered equivalent to the friction enhancing material is applied in a pattern.

As to claim 17, since the package of Soto'069 is made from the semi-permeable material, therefor, the friction enhancing material is applied on the semi-permeable material.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-20 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over Soto et al. (5,866,069; hereinafter Soto'069) in view of The Related Prior Art on pages 1-2 of the instant patent application (hereinafter The Related Prior Art) or Hoekstra (6,986,730). Soto'069 discloses the sterilization package for enclosing the medical products as above having most of

the claimed limitations includes the package formed from TYVEK which is a gas permeable material (column 1, lines 66-67).

To the extent that Soto'069 fails to show the material of the package being impermeable to contaminating microorganisms, The Related Prior Art teaches that it is old and conventional of providing a package for receiving a medical product to be sterilized comprising two film layers with one film formed of a laminate of clear polyolefin and polyester which is considered equivalent to an impermeable material which is impermeable to sterilizing gases and contaminating microorganisms and an another film formed from TYVEK which is permeable to sterilization gases and impermeable to potentially contaminating microorganisms. Hoekstra shows a pouch (100) for packaging medical devices comprising a first layer (30) formed from a thermoplastic gas impermeable layer and a second layer (20) formed from TYVEK which is a gas permeable microbial barrier defined as permeable to sterilizing gases and impermeable to microbial contaminants (column 3, lines 51-56). It would have been obvious to one having ordinary skill in the art at the time the invention was in view of The Related Prior Art or Hoekstra to modify the package of Soto'069 so the TYVEK package comprises a material that is impermeable to contaminating microorganisms for better protecting the contents disposed within the package.

As to claim 20, it would have been obvious to one having ordinary skill in the art in view of The Related Prior Art or Hoekstra to modify the package of Soto'069 so the package comprises at least a portion of the barrier film being formed of an impermeable material and at least a portion of the barrier film being formed of the semi-permeable material for better protecting the medical products disposed within the package.

7. Claims 1-20 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over The Related Prior Art on pages 1-2 of the instant patent application (hereinafter The Related Prior Art) or Hoekstra (6,986,730) in view of The European Publication No. 0 304 255 to Katila or The European Publication No. 0 863 087 to Hoefte or the German Patent No. 1 779 373 to Vollmer. The Related Prior Art or Hoekstra discloses the sterilization package as above having all the limitations of the claims except for at least a portion of an outer surface of the package having thereon a friction enhancing material and the friction enhancing material being applied on the impermeable material in a pattern while not impeding permeation of sterilizing gases. Katila teaches a package formed from a conventional foil (1) comprising a pattern of friction surface (2) disposed on an outer surface of the package to facilitate stacking of the packages (see abstract and column 1, lines 1-10). Hoefte shows a package comprising an outer surface and an anti-slip layer formed from a silicone based material disposed on the outer surface of the package to prevent the package slipping when the package is staked with other packages (see abstract). Vollmer suggests a bag comprising an outer surface and anti-slip coating disposed on the outer surface of the bag to prevent slipping of the bags on storage or stacking. It would have been obvious to one having ordinary skill in the art at the time the invention was made in view of Katila or Hoefte or Vollmer to modify the package of The Related Prior Art or Hoekstra so at least a portion of the outer surface of the package comprises a friction surface or an anti-slip layer/friction enhancing material to prevent the package from slipping during stacking with other packages and the friction enhancing material is applied in a pattern while not impeding permeation of sterilizing gases to allow the package to be sterilized.

Response to Arguments

Applicant's arguments filed on 4/25/2008 have been fully considered but they are not deemed to be persuasive.

Applicant's argument with respect to Soto on page 7 of the remarks is noted. This is not persuasive because Solo discloses is outer surface of the package is coated with the silicone material/friction enhancing material and the silicone is applied by spraying systems/pattern and the package can be sterilized (column 4, lines 37-47) which is considered equivalent to not impeding permeation of sterilizing gases.

Applicant argues "there is nothing in the references that would suggest modifying Soto to include the friction enhancing material ..." on page 8 of the remarks is noted. This is not understood because there is nowhere in the rejection that the Examiner modifies Soto to include the friction enhancing material applied in a pattern while not impeding permeation of sterilizing gases since such limitation has been disclosed by Solo (see above).

Applicant's arguments with respect to Solo on page 9 of the remarks are noted. They are not persuasive because even if Solo teaches coating the entire sheet of material with silicone is considered equivalent to a pattern as claimed and the package can be sterilized with the coating is considered equivalent to not impeding permeation of sterilizing gases.

Applicant's arguments with respect to The Related Prior Art and Hoekstra on pages 9-10 of the remarks are noted. They are not persuasive because The Related Prior Art or Hoekstra is relied upon for nothing more than providing a package for receiving a medical product to be sterilized having two film layers with one film formed of a laminate of clear polyolefin and polyester which is considered equivalent to an impermeable material which is impermeable to sterilizing gases and contaminating microorganisms and an another film formed from TYVEK which is permeable to sterilization gases and impermeable to potentially contaminating microorganisms.

Applicant's arguments with respect to Katila or Hoefte or Vollmer on pages 10-13 of the remarks are noted. They are not persuasive because Katila or Hoefte or Vollmer is relied upon for nothing more than providing a package having a pattern of friction enhancing material disposed on an outer surface of the package to facilitate stacking of the packages.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is 571-272-4552. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

lkb
June 19, 2008

/Luan K. Bui/
Primary Examiner
Art Unit 3728